Health Information Technology Standards Committee
Final
Summary of the February 29, 2012, Meeting

KEY TOPICS

1. Call to Order

Mary Jo Deering, Office of the National Coordinator (ONC), welcomed participants to the 33rd meeting of the HIT Standards Committee (HITSC). She reminded participants that this was a Federal Advisory Committee meeting, with an opportunity for the public to make comments, and that a summary of the meeting would be available on the Web site. She conducted roll call, and the following Committee members were in attendance:

Jonathan Perlin, Hospital Corporation of America (HITSC Chair)
John Halamka, Harvard Medical School (HITSC Co-Chair)
Farzad Mostashari, National Coordinator for Health Information Technology
Dixie Baker, Science Applications International Corporation
Anne Castro, BlueCross BlueShield of South Carolina
Christopher Chute, Mayo Clinic College of Medicine
Tim Cromwell, Department of Veterans Affairs
John Derr, Golden Living, LLC
Lorraine Doo, Centers for Medicare and Medicaid Services
Floyd Eisenberg, National Quality Forum
Jamie Ferguson, Kaiser Permanente
Leslie Kelly Hall, Health Wise
Stan Huff, Intermountain Healthcare
Elizabeth Johnson, Tenet Healthcare Corporation
David Kates, Prematics, Inc. (for Kevin Hutchinson)
Rebecca Kush, CDISC
Arien Malec, RelayHealth
David McCallie, Cerner Corporation
Nancy Orvis, Department of Defense (Health Affairs)
Wes Rishel, Gartner, Inc.
Rebekah Rockwood, Markle Foundation (for Carol Diamond)
Christopher Ross, MinuteClinic
Walter Suarez, Kaiser Permanente
Sharon Terry, Genetic Alliance
Jim Walker, Geisinger Health Systems

Deering then turned the meeting over to HITSC Chair Jonathan Perlin.

2. Opening Remarks/Review of the Agenda

Perlin welcomed participants to the meeting, noting that the use cases that are being developed now are so sophisticated that they are reflective of real-world activities associated with providing services for patients, supporting transitions, and fostering teamwork in the delivery of care. He thanked Committee members for their work and commented that this meeting would involve

reviewing the response to the Notice of Proposed Rulemaking (NPRM) and identifying future activities as they relate to the glide path for stages 2 and 3, and the intent of meaningful use.

HITSC Co-Chair John Halamka reminded the Committee that its 2012 workplan was broken out into quarterly activities. The January, February, and March activities are highlighted by a review of the NPRM, which is generally consistent with HITSC Workgroup recommendations. Also included in activities for this quarter is a review of the Nationwide Health Information Network (NwHIN) Exchange comments and quality measure standards. The second quarter of 2012 work will include additional discussions on the supporting components of the NwHIN and provider directories. Of interest as the Committee reviews the NPRM are the use of transport standards, specifically the SOAP and S/MIME SMTP standards of Direct and Connect, as well as the supporting components. The HITSC will also address Query Health and radiology standards (there is a menu set criteria that indicates that 40% of all radiology images ordered should be displayable in an electronic health record [EHR]). Also for consideration are issues such as governance as it relates to the Standards and Interoperability (S&I) Framework—is it going to be government-funded activity forever? Is it going to be privatized? How should it best articulate with the HITSC and standards development organizations?

Before moving forward with the agenda, Perlin noted that the HL7 and currently scheduled May 16 HITSC meeting overlap; the ONC is working to find a new date and time for the May HITSC meeting that is compatible with Committee members' schedules. He referred members' attention to the minutes of the January meeting and asked for corrections or amendments. Hearing none, he declared the minutes approved as written.

> **Action Item #1:** The minutes of the January 2012 HITSC meeting were approved as written.

3. Proposed Rule Standards & Certification Criteria: 2014 Edition

Steve Posnack of ONC noted that the new NPRM includes new language related to certification criteria—there will be two sets of certification criteria in play at the same time, and therefore the need to distinguish between both of them. The ONC has worked to develop distinctions between the previously adopted certification criteria and the set of certification criteria that is being proposed so far. The already adopted certification criteria are now referred to as the "2011 edition;" the criteria proposed for adoption are now referred to as the "2014 edition." Posnack explained that the ONC has merged and split some of the certification criteria. In the 2011 edition, there are 41 criteria plus an optional one. In the 2014 edition, there are 50 criteria plus an optional one.

Posnack noted that there are three categories of certification criteria: (1) new certification criteria (capabilities that had not been specified for certification criteria and have never been adopted before), (2) revised certification criteria, and (3) unchanged certification criteria. It's all set through new, revised and unchanged as I go forward. And each of them has a little bit of nuance to them. These are all the new certification criteria that we've adopted. He presented the new, revised, and unchanged certification criteria within ambulatory and inpatient, inpatient only, ambulatory only categories.

The ONC is redefining certified EHR technology to provide greater flexibility and a clearer definition of certified EHR technology and its requirements, promote continued progress towards increased interoperability requirements, and reduce regulatory burden (particularly with regard to Executive Order 13563). Posnack presented a series of slides to demonstrate the shift in the definition of certified EHR technology, noting that the definition moving forward for 2014 is more dynamic and driven by the stage of meaningful use that an eligible provider (EP) would need to meet starting in the 2014 EHR reporting period. He emphasized that the definition of certified EHR technology is equally important for both EHR technology developers and EPs, because they need to use it to demonstrate meaningful use. The definition of certified EHR technology is specified in ONC's regulations.

Posnack reviewed the certification criteria required to satisfy the definition of a "base" EHR, noting that a base EHR does not have to be one solitary EHR technology; rather, it is about the certification criteria that constitute the capabilities that are part of what makes it meet the definition of a base EHR. He noted that the revised definition of certified EHR technology is driven by meaningful use and the stage and pathway of meaningful use an EP will need to meet. Starting with a base EHR, every EP must have EHR technology with the capability certified to meet the definition of a base EHR, regardless of stage. The path diverges at the point of the meaningful use core and the meaningful use menu that are available to an EP based on the stage of meaningful use that they seek to achieve. Further flexibility is introduced in that it is up to the EP to ensure that they have EHR technology that has been certified for the capabilities that they need to meet for the menu set objectives and measures that they seek to achieve for the stage of meaningful use that they are going to meet. An EP in stage 1 will only need to have EHR technology at a minimum that has been certified to support the stage 1 objectives and measures.

Posnack presented a slide showing the 2014 edition of certified EHR technology applied to meaningful use stage 2. He described the proposed ways that an EP can meet the certified EHR technology definition—by having a complete EHR (which by definition has been certified to all of the applicable certification criteria), or a combination of EHR modules that is equivalent to a complete EHR. In 2014, when the proposed new definition of certified EHR technology is implemented, all EPs will need to use EHR technology that has been certified through the 2014 edition certification criteria.

Posnack explained that there is no such thing as being "stage 1 certified" or being "stage 2 certified." The EHR technology is certified for the editions of certification criteria that the ONC has incorporated into its rule making with respect to the 2011 and 2014 editions. He asked Committee members to take this message back to their respective organizations and stakeholders.

Posnack then walked the Committee through a description of proposed 2014 edition standards in the categories of transport, functional, security, content exchange, and vocabulary/code sets.

With regard to the permanent certification program, additional changes have been made. Moving forward, the temporary certification program will be sunsetting. Therefore, the ONC is renaming the permanent certification program as the "ONC HIT Certification Program." Revisions to the EHR module certification requirements are being made in terms of privacy and

certification; other minor changes are also being made to make certification more efficient. Certain new criteria are being applied in terms of automated numerator recording, non-percentage-based measures, and safety-enhanced design. The ONC is also working to enhance the public commenting experience. A Word version of the rule is now available online, and the Office will be making a comment template and other useful grids and materials available. Posnack reminded the group that there are three ways to provide comments: (1) mail (snail/express), (2) electronically through regulations.gov (the preferred approach), and (3) hand delivery. He also reminded the group that positive comments about what is beneficial and effective are just as valuable and useful as critical comments that identify needs, gaps, deficiencies, etc.

4. Comments From the National Coordinator

Before proceeding with Committee discussion on the standards and certification criteria NPRM, National Coordinator for Health Information Technology Farzad Mostashari addressed the Committee. Mostashari reminded Committee members Department of Health and Human Services Secretary Kathleen Sebelius recently announced data on the dramatic increase in the adoption of EHRs by hospitals over the last year. This increased adoption nears, and in some ways, exceeds the increase seen among outpatient providers. These are promising trends.

At a recent meeting of the Healthcare Information and Management Systems Society (HIMSS), Mostashari spoke and emphasized that the regulations in many ways are staying the course. At that meeting, he toured the exhibit floor and heard from many about how much time it takes not just to incorporate the certification criteria into EHRs, but also to actually make meaningful use of those certification requirements and incorporate them efficiently and effectively into workflows.

Mostashari noted that one of the most important functions that Federal Advisory Committees such as the HITSC have provided in this field is a sense of predictability that avoids creating a feeling of uncertainty in the industry and its development process. There are, however, policy areas in which the ONC has pushed harder than the HITSC or Health IT Policy Committee (HITPC) in distinct ways. The Office is grateful to be in the position of being able to propose a single standard medications and problem list clinical diagnoses, a single standard for patient care summary, and a single standard for laboratory results, and the ubiquitous availability of protocols for transport.

5. Discussion on the Proposed Rule Standards & Certification Criteria: 2014 Edition Presentation

Perlin then turned the Committee's attention toward a discussion of the presentation given by Posnack. Halamka commented on the need to incorporate TLS for patients to be able to access data (which is not specifically called out as a transport standard, but it a mechanism of accessing data). He also pointed to the need to appropriately qualify the means by which discharge medication communication takes place and the need for clarity with regard to transmitting imaging data.

Rishel asked about certification and the need for EPs to track and ensure that their technologies are certified. Posnack indicated that the ONC can likely play a role in making resources

available to providers (e.g., a certified HIT products list) to help them ensure that they have the requisite certification criteria covered. EPs will have to make efforts to ensure that they have the appropriately certified technology in place, but forms and checklists could be developed to help ease this activity. Rishel asked if ONC was going to specify a standard format for the audit log. Posnack responded that the data need to be captured, but there is no best practice required for certification at this point.

Walker suggested that it would be useful for the user community if the ONC identified any issues associated with using only a 2011 certified EHR compared with only a 2014 certified EHR. He also noted that it may be difficult to change the culture of identifying technologies as "meaningful use stage 1 certified," or "meaningful use stage 2 certified." Walker also commented that it may be helpful to keep ICD-10 out of certification criteria if possible—it will also help the community if organizations are given some assistance in thinking through the costs and benefits of adopting certified technologies. Posnack clarified that in terms of the culture of identifying technologies as being "meaningful use stage 1 certified" and the like, the only thing that providers will need to know is that their EHR technology is "2014 edition certified," regardless of meaningful use stage.

Ross reminded the group that the Implementation Workgroup has been working to develop test cases both to improve the observability and automation of tests. These efforts and the content of Posnack's presentation should be matched up as seamlessly as possible. Posnack offered to work with the Implementation Workgroup in this regard. Ross also asked about the combination of two vendor products and about the possibility of the NwHIN Power Team sharpening the language regarding the emergence of RESTful transport. Posnack acknowledged that the proposal he presented at this meeting does not address having two separate modules from different vendors. Mostashari added that the ONC is in the process of exploring RESTful interfaces and is trying to operationalize it in a responsive way.

Suarez asked for clarification regarding the 2014 edition of certified criteria. Posnack explained that for anyone who has EHR technology that has been certified through the 2011 edition certification criteria, they are "good to go" through 2013. The ONC is proposing to allow users to obtain upgrades so that they can transition to and meet 2014 criteria without regulatory interference. Mostashari added that the intent is to spread out the time to allow organizations to upgrade to the 2014 edition and have that be backward compatible so they can continue to meet the 2011 edition requirements in stage 1.

Derr recognized Mostashari for his dynamic leadership at the HIMSS meeting and thanked the ONC for including health care providers other than the ones that are eligible (e.g., those in post-acute care) in the proposed rule.

Eisenberg commented that the certification rule is a balanced approach that clearly takes into consideration the large number comments that have been submitted. With regard to encounter diagnoses, he suggested that having the diagnoses in different formats may be somewhat problematic. He also noted that with regard to procedures, SNOMED was not included, and asked if that was an error of omission or if it is not in the rule. It was noted that in the transmittal letter from the HITSC, it was recommended that SNOMED be included.

Baker voiced support for the specification of Direct and Exchange for EHR exchange, and suggested that including the third reserve category will hopefully accommodate a RESTful third transport. She expressed concern about the omission of Transport Layer Security (TLS) as an acceptable secure transport for appropriate purposes. In the preamble, TLS is mentioned as an acceptable transport, but in the body of the regulation itself, it is omitted. She added that in the consumer section, she would call out TLS as acceptable for consumer communications.

Hall noted that she is encouraged by the descriptions of the modular approach. The real world needs to put together modules that come with those acquisitions, and being able to mesh that easily for certification and attestation is a real need. More clarity around those modules and how that can be used is important. Clarity around care coordination and patient engagement is also needed moving forward.

Malec pointed out that allergy terminology or adverse drug event terminology was not specified, and Fridsma asked that this item be reconsidered. It was noted that in the transmittal letter, the Committee recommended RxNorm and NDF-RT for the medications, and SNOMED for describing the allergy. Malec noted that the definition of the term "XDR" appears incorrectly in the regulation, and suggested that the section that discusses XDR and XDM for directed messaging, with SOAP being optional, could be rewritten because it introduces inconsistencies. He suggested that either that the SMTP, S/MIME specification be required and the XDR, XDM specification be optional, or to see that both are required, including SOAP as a required transport. McCallie noted that the intent seems to be that XDR is optional, but it is not completely clear, perhaps the reference documentation is unclear.

Malec also expressed enthusiasm regarding the level of focus on patient engagement that appears in this proposed rule and in the CMS proposed rule. However, he voiced concern that the natural EHR vendor response is to utilize a patient portal. For an effective patient portal, there are significant privacy and security is hard issues—overcoming those while making the portal user-friendly for patients is also extremely difficult.

McCallie echoed Malec's earlier comment about bringing clarification to XDR and SOAP and what the exact intent is in that area. He also commented that currently, there is no good way to know what the processing technology on the other end of an asynchronous message is. The technical constraint would require something new that would need to be tracked (and would add a burden). McCallie also noted that there is a fear or concern regarding the ICD-10/SNOMED problem list confusion which could lead to the unintended consequence of no one using the problem list because it is too burdensome.

In response to a question from Murphy on clinical quality measures certification, Posnack explained that the ONC expects the EHR to acknowledge and be able to capture all of the data elements specified in the clinical quality measures, as well as export that information so that it can be consumed by another type of EHR technology. Eisenberg commented that it may not be beneficial to have capturing the data and exporting driven by specific measures.
Going back to an earlier comment regarding the omission of drug allergy adverse event reporting, Orvis suggested that it should be fairly easy to add it back in a clearly articulated fashion. She noted that for 6 years, the DoD and VA have been exchanging medication allergies

at RxNorm with the NDF-RT and SNOMED for the conditions. She echoed Malec's concern about the possibility of there being a plethora of patient portals. Having a "one-stop shop" for everyone within a group is important as a single access point of information. Gartner cautioned that having concern about there being a plethora of patient portals should not be a rationale for having no patient portals. He also noted that there are more issues to be unearthed between now and 2014 in the consolidated CDA. A process for identifying and resolving those issues that is available freely to the community and that has a faster turnaround than a full HL7 ballot cycle is needed.

6. Stage 2 HER Certification: NLM Vocabulary Update

Betsy Humphreys, National Library of Medicine (NLM), explained that her presentation would focus on issues related to SNOMED CT and how it does or does not connect with ICD-10-CM or ICD-9-CM. One of the specification and certification criteria that has garnered a great deal of attention is the fact that SNOMED CT is proposed as the sole candidate for the problem list. Humphreys noted that there are a number of assets related to SNOMED CT designed to help people who want to implement them.

She highlighted a few issues that the NLM has been working on in collaboration with the International Health Terminology Standards Development Organization (IHTSDO) over the past few years. One is a perceived slow rate or speed of new content additions to SNOMED CT. The IHTSDO is working on infrastructure to address this, both in the tooling but also in the expansion of high-level consultant terminologist selection and training. This is increasing the capacity for making high level decisions and moving ahead. As of earlier this month the consultant terminologists are now able to edit directly into the international release of SNOMED. The NLM has created the U.S. extension, a way to more quickly get SNOMED CT modeled content for things that are of particular interest to the United States. There is also a U.S. content request system.

Additional issues being addressed include transitioning from the use of ICD-9-CM for problems and the use of SNOMED CT to generate encounter diagnoses (in ICD-10-CM or ICD-9-CM) for billing/statistics. Humphreys noted that The IHTSDO has made available conceptual mapping from SNOMED CT to ICD-9-CM, and the NLM has released synonymous mappings between ICD-9-CM and SNOMED (available within the UMLS metathesaurus). Coming soon, the NLM plans to release a trial map for evaluation, which maps heavily used ICD-9-CM codes based on CMS data to SNOMED CT. Humpries noted that these activities are the result of international cooperation and collaboration with groups within the United States. In producing this map, the NLM leveraged procedures, data, and tools from the IHTSDO, from the United Kingdom's National Health Service Terminology Center, and also data from Kaiser Permanente. Humphreys described the Interactive Map-Assisted Generation of ICD Codes (I-MAGIC) algorithm, which utilizes the SNOMED CT to ICD-10-CM map in a real-time, interactive manner to generate ICD-10-CM codes.

Humphreys noted that RxNorm is based on responding to recommendations from this group and others. It is very capable of representing both medications and allergies to medications or ingredients in medications. There was a recommendation from the Vocabulary Task Force and the Clinical Quality Working Group to represent inert ingredients within RxNorm. In terms of

LOINC, based on input from the HITSC and other groups the NLM has two subsets that are designed to help people move forward in terms of mapping internal items or implementing LOINC. She concluded her remarks by asking what else the NLM can do to help support meaningful use of these vocabularies in the pursuit of the meaningful use of EHRs.

Discussion

McCallie noted that there are many cases for which a single ICD-10 code would require a post coordinated SNOMED code in today's world to represent it. Most tools that capture SNOMED do not capture post coordinated SNOMED. Humphreys indicated that the I-MAGIC application as shown was not using post coordination on the SNOMED side of it. McCallie noted that if the knowledge that drives the rules is available, then it would be feasible for people to incorporate those rules into systems that, for example, parse the text of the node looking for laterality so as not to have to make the doctor pick from a list, because the extra overhead of managing pick lists is burdensome. Humphreys added that the NLM is seeking input on the application so that improvements can be made in subsequent versions.

Malec noted that consideration needs to be given in the certification testing to the role that subsets have to play in the context of transitions in care and in the context of pushing information to patients. Having a common subset that everybody knows is important. He added that it is often very difficult to get real interoperability to reactions to classes of medications. Humphreys agreed that this should be an area of focus.

Orvis asked about organizing a clinical document taxonomy under LOINC. Huff indicated that there is some work ongoing in this area. Ross noted that currently, only the VA NDF drug classes are present in the RxNav application, many of the other NDF-RT classes are not present at this time. Furthermore, the ability to capture more than one drug class per agent is going to be a crucial level of functionality as RxNorm evolves and matures.

Ferguson noted that recently, the IHTSDO approved a pilot program for implementation consultants for more broadly disseminating SNOMED implementation expertise. A U.S. version of this program would be beneficial. Humphreys agreed, adding that the IHTSDO resource will be useful moving forward. Hall suggested that as more patient engagement principles are beginning to be defined, building upon the work that Kaiser has done with the NLM would be good as a precursor to a future environment that will include more consumer-friendly terms and more patient involvement and integration into the HIT ecosystem. Humphreys acknowledged that these are important issues, and ones that the NLM is concerned about, particularly in terms of providing access to consumer health information.

7. NwHIN Power Team – Update and New Charter

Dixie Baker of Science Applications International Corporation noted that the group has a new charter and new members. She presented a list of the Power Team's membership. Baker noted that in September 2011, the HITSC transmitted a letter to the ONC requesting that the Office perform additional investigation on exchange specifications, specifically in the areas of: (1) assessment of specification complexity, adoption, deployment; (2) implementation challenges; and (3) alternatives used for exchanging health information across enterprises. The ONC posted

a series of questions on the HIT FACA blog, and received 20 responses from a broad sample of organizations. Baker listed the relevant responders, noting that two individual responses were eliminated because they did not address the questions.

The response from the Exchange Coordinating Committee indicated that implementations of the core specifications are currently operational within a limited production context and demonstrate value to participants. As of September 2011, 20 organizations were exchanging data in limited production. The Exchange Coordinating Committee is developing a business and transitional plan to guide the Exchange to a sustainable, scalable, and efficient public-private model. The core exchange specifications can serve as the basis for health information exchange innovation and as a critical element in nationwide health information infrastructure.

Baker summarized feedback from other organizations and vendors with the following points:

- All implementations of the Exchange specifications are for exchanges with federal agencies and one large organization.
- All of the current implementations of the Exchange specifications are in limited production mode and have not been used for large-scale production exchange.
- Complexity seems more related to specifications themselves than to the Exchange architecture.
- The lack of scalability of identity management limits the use cases for which patient discovery is applicable.
- The core exchange specifications have the robustness required to meet the needs for comprehensive health information exchange, but require substantial efforts to reduce optionality and indirection, reduce ambiguity, improve scalability and testing, and reduce the cost of implementation.
- Suggestions included: (1) simplifying specifications by reducing optionality and indirection, (2) consolidating all of the core specification documents into a single document or repository, and (3) improving the testability of specifications.

The NwHIN Power Team's new charter no longer focuses exclusively on the NwHIN or on Exchange, but builds on the criteria it recommended and used during phase 1 of the Power Team. The group's purpose now is to provide guidance and feedback to the ONC for the development of objective criteria for evaluating the readiness of specifications for adoption as national standards. The goal of the NwHIN Power Team is to support the development of comprehensive, objective, and to the extent practicable, quantitative criteria for evaluating technical specifications as candidates for national adoption as standards into the following classes: (1) ready for national adoption, (2) emerging, and (3) pilot/domain specific.

Discussion

Fridsma commented that having explicit criteria also helps inform the ONC and industry about where to put their investments. If something requires more pilot and real-world work, the appropriate investment can be made. When asked about addressing scalability issues, Baker explained that simplifying could be considered in criteria. Particular problems, such as patient identity, could be subsetted out. Baker noted that the first step for the new Power Team will be to define a set of use cases to help constrain the types of specifications it will be considering.

Hall asked about accounting for innovative technologies, and suggesting not tabling completely a discussion of how patients are identified, because it will be a cornerstone of how patients enter the NwHIN. Baker noted that innovative technologies will not be excluded from consideration; however, unless they achieve traction and widespread adoption, they likely will not become part of national standards.

Orvis pointed to the need to narrow the use cases being considered by the Power Team, which should continue to point out where there are policy issues. Patient identification is critical and may represent a stumbling block if not addressed appropriately. Walker commented that if the criteria could be rated in operational terms, they would be better understood and used. Baker agreed, noting that the group's charter includes language indicating "quantifiable to the extent possible."

Perlin summarized with the following points: (1) identification of the patient and scalability are important areas, (2) innovative or leapfrog technologies should be considered, (3) policies are needed that permit development without penalizing early adopters or undermining previous work. Ferguson noted that the ONC published some standards readiness criteria in 2006, which covers many of these topics. He urged Committee members to review this document to see if any of that previous work can be applied here.

8. HIT Policy Committee 2012 Work Plan

Paul Tang, HITPC Vice Chair, explained that stage 1 about getting systems on line and getting data structured as much as possible into these systems. Stage 2, which is the focus of the NPRM, focuses on health information exchange and care coordination. Stage 3 is where outcomes are more readily measured, assessed, and improved at both the individual and community levels. To help describe HITPC policy support of HIT-enabled transformation in the coming years, Tang presented a timeline with milestones for HIT-enabled transformation, beginning with HITECH policies in 2009 and culminating in stage 3 outcomes measurement and improvement in 2015 and beyond.

In terms of HITPC's 2012 quarterly work plan, Tang explained that the first quarter has included a focus on meaningful use stage 3 principles and focal areas, the meaningful use stage 2 NPRM, the governance Advanced Notice of Proposed Rulemaking, and stage 3 quality measures. The second quarter of 2012 will feature topics such as a quality measures lifecycle hearing, a patient-generated data hearing, information exchange, and a Certification/Adoption Workgroup discussion on EHR safety. Quarter three will include a focus on meaningful use stage 3 draft recommendations, the Certification/Adoption Workgroup working on long-term and post-acute care, and the governance NPRM. In the fourth quarter of 2012, the HITPC will work on reconciling meaningful use stage 3 recommendations with the stage 2 final rule, soliciting feedback on draft stage 3 meaningful use recommendations, consumer eHealth, and revising the strategic plan.

With regard to 2013, the HITPC expects to issue a Request for Comment, as it has done for past stages, as a chance for the public to provide feedback before recommendations are submitted to the ONC and CSM. Those comments will likely be due in February, and in March, a summary of the comments will be produced that incorporates input from the HITSC. In the second quarter

of 2013, the HITPC Meaningful Use Workgroup will reconcile the comments from the public and from the HITSC, and in June will present final stage 3 recommendations for HITPC approval. In July 2013, the HITPC will submit its transmittal letter to the Department of Health and Human Services.

Discussion

Before starting the discussion, Tang noted that Committee members received a formal letter from the HITPC with its feedback from the field regarding the clinical quality measures. The letter includes some issues identified by the HITPC as well as some proposed solutions. Perlin added that the letter will be formally transmitted to Walker in the Clinical Quality Measures Workgroup for consideration. Walker noted that the deadline for responding to the letter is March 9.

Malec commented that if there are lead-time activities for which there is a capability that is necessary for a for a policy that is not well established or does not have a well-established standard today, the earlier in the life cycle the HITPC knows about it, the more lead time there can be to start working through issues. Malec suggested that there may be some unfinished work in care coordination—in particular, CMS and ONC pushed a little further than the HITPC recommended in terms of the plan of care. For example, in post-discharge cases where specific follow up tests or procedures or visits are indicated, expressing those follow up items in a structured format would potentially be an interesting area where there needs to be more standards alignment to policy goals. Malec also pointed out the strong efforts of the Privacy and Security Tiger Team.

Huff noted that the incentive money at best has a temporary increase in the number of resources that groups like his have to implement all of their information systems. These groups are chasing the incentive money at the expense of other activities. These groups are being increasingly challenged to try to determine whether something that is good and required as a measure for meaningful use is in fact the best thing for their respective organizations. Mostashari commented that it is important to be conscious about not adding things just for the sake of adding them.

Huff cautioned that some groups are essentially "teaching to the test" and not fundamentally building an infrastructure that allows them continuous quality improvement within their system. These groups are more or less hard coding exactly the requirements of meaningful use into the system, not in a sustainable way, but in a one-off kind of way. Orvis added that if clinical schools, nursing schools, allied health schools, etc. are not training their personnel to use structured vocabulary and terminology, which is not reimbursable for anybody other than physicians, the type of problem described by Huff will always exist. Tang noted that one important program at ONC involves educating the workforce in this regard.

9. HITSC Response to the NPRM

Halamka discussed HITSC plans to respond to the NPRM in terms of distributing efforts and coordination so that the collective effort is as helpful to the ONC as possible. Halamka suggested that it would be reasonable to use the Committee's Clinical Operations, Clinical Quality, and Privacy and Security Workgroups as organizing principles, with calls led by

Workgroup Chairs who would gather input from their respective Workgroups and forward it to Halamka and Perlin before presentation to the ONC. Individual organizations would also have an opportunity to respond.

Hall suggested that a focus on patient engagement and consumers should be formed to generate a response to the NPRM from that perspective, and agreed to lead such a group. Halamka agreed, and tentatively called the group the Patient Engagement Affinity Group.

Walker noted the need to ensure that any cross-cutting issues are not missed but are captured and sent on to the ONC.

> **Action Item #2:** Leslie Kelly Hall agreed to lead a new Patient Engagement Affinity Group to frame and organize HITSC responses to the NPRM in this area.

10. Clinical Quality Workgroup Update

Walker commented that the Workgroup is reforming, with a strong interest and commitment from existing members. At its last meeting, the group made it halfway through reviewing and validating its new charter. New members representing new skill sets are being added. The Workgroup plans for form two Tiger Teams, one focused on coordinating efforts with the HITPC regarding better alignment of quality measure expectations with EHR capabilities, and one focused on clinical quality value set harmonization, alignment, and distribution.

Discussion

Fridsma thanked Walker for his leadership and noted that this Workgroup represents an opportunity for the HITSC and HITPC to work closely together. There may be an opportunity for both Committees to hold a joint session on policy and standards as they relate to quality measures. Moving forward, it will be increasingly important for the HITPC and HITSC to work together on these issues.

11. Updates from the ONC – S&I Framework

Fridsma explained that achieving interoperable health care information systems involves: (1) enabling stakeholders to come up with simple, shared solutions to common information exchange challenges; (2) curating a portfolio of standards, services, and policies that accelerate information exchange; and (3) enforcing compliance with validated information exchange standards, services, and policies to assure interoperability between validated systems. Within ONC's Office of Standards and Interoperability, the enabling stakeholder for these activities is represented by the S&I Framework activities.

Fridsma explained that the building blocks of health information exchange include vocabulary and code sets, content structure, transport, security, and services. The NwHIN will specify how these building blocks can be assembled together to form solutions that address health interoperability issues. In thinking strategically about what should be developed within the S&I Framework or as part of ONC's portfolio, strategic drivers (e.g., health outcome policy priorities), tactical drivers (e.g., HIT focus area/meaningful use alignment), and standards

challenges (e.g., S&I initiatives) drive value and the direction. Clinical use cases, technical standards, and infrastructure lower costs by enabling reuse.

Fridsma described the foundation s for a learning health system and identified characteristics of the S&I Framework that are unique. The S&I Framework approach is to create a collaborative, coordinated, incremental standards process guided by the ONC with input from Federal Advisory Committees, enabled and led by an open community of industry participants who are engaged in solving real-world problems. Value created through this approach: (1) solves real-world issues to enable health information exchange, (2) creates leverage for the ONC and other initiative sponsors by harnessing the expertise and passion of the community to solve problems, and (3) empowers the community to create the best solutions for interoperability and standards adoption.

Fridsma then described how the S&I Framework enables a reusable platform, identifying the asset, the audience/beneficiaries, and the value created. He discussed the application of the S&I Framework process to standards challenges and how standards analysis and harmonization are operationalized. He noted that when it comes to supporting S&I Framework initiatives, it is not a "one size fits all" scenario. Some activities are so strategically important and so critical to advancing interoperability that they have the full weight and support of the ONC behind them (e.g., transitions of care). Other activities may only require only strategic types of support (hybrid resources in which there are targeted investments on specific components). The ONC is engaging members of the community to obtain feedback about how to best move the S&I Framework forward.

Discussion

When asked about moving emerging innovative approaches through the S&I Framework, Fridsma explained that if there is a well adopted Internet-based standard that is not specific to health care but could be fundamental in terms of doing discovery of certificates, directories, etc. in an expeditious and secure manner while meeting the requisite criteria, it could be included in S&I Framework activities.

Rishel noted that the work being done by the California Healthcare Foundation is not regional (which was used in Fridsma's presentation as an example of an S&I Framework activity receiving strategic support) despite the organization's name and location. It is nationally represented, nationally supported, and the work it is doing to test its specifications is not in any way limited to California. He asked about whether issues included in S&I Framework activities are being considered by other consensus bodies and commented that his belief is that the S&I Framework has suffered from a sense of redundancy among many participants because these issues are discussed at length in other organizations as well. He also suggested that more broad industry participation would be useful.

Ferguson asked how the NIEM fits within the S&I Framework. Fridsma noted that the NIEM, as a process within the federal government, established a standards-like process among state, local, and tribal organizations that would help them provide some standards. That has produced value within the federal government and there is a desire to reduce costs and not have redundancy across the federal government using NIEM frameworks. It is not clear how the NIEM fits in, but

the ONC is actively engaged with the NIEM community to pursue this issue.

Murphy and Rishel asked about implementation, Rishel in particular noting the need for a strong home for implementation support within the ONC.

12. Public Comment

Lindsay Hoggle, Academy on Nutrition and Dietetics (AND, formerly the American Dietetic Association), commented that if meaningful use is the "floor" as Mostashari had referred to it earlier in the meeting, nutrition and diet orders should be included somewhere above that floor. Some patients have very important dietary restrictions. Any omission in a transition of care or any other exchange of data of that information can be critical. She also pointed to the need to ensure that there are structured nutrition terms included in the EHR. In terms of consumer engagement, nutrition, diet, and exercise are one of the main topic areas that patients search for online. The AND has been working with several experts and on the HL7 Patient Care Committee Allergy Workgroup towards developing a standard for food allergies to help ensure that no mishaps occur from using EHRs.

Tom Bizzaro, First DataBank, noted that his group has an intense interest in the designation and use of national standards and national standard-related vocabularies. In terms of the codification of drug allergens and specifying a standard vocabulary for those allergens, it makes sense that the codification of allergies to dispensable drugs, drug ingredients, and recipient ingredients use RxNorm, and he endorses this. His group also supports the interoperable transfer of allergy drug class information in a standard vocabulary for drug class, which is required to support the interchange of this important health information.

Robin Raiford, Allscripts, presented the Committee with the final standards rule from stage1, the 2014 criteria, the stage 2 NPRM of measures, objectives, numerators, denominators, exclusions, and thresholds on one piece of paper. She indicated that she would send it to Perlin along with a link so that the Committee can access it electronically and disseminate it.

SUMMARY OF ACTION ITEMS:

Action Item #1: The minutes of the January 2012 HITSC meeting were approved as written.

Action Item #2: Leslie Kelly Hall agreed to lead a new Patient Engagement Affinity Group to frame and organize HITSC responses to the NPRM in this area.